June 14, 1999

MEMORANDUM

SUBJECT: Oxamyl Reregistration. Celery Residue Data Supporting PHI Change, REVISIT. Guideline 860.1500 Crop Field Trials.

MRID 44654301
DP Barcode: 256447
Chemical No. 103801
Case No: 0253

FROM: John S. Punzi, Ph.D., Chemist
Reregistration Branch 2
Health Effects Division [7509C]

THRU: Alan Nielsen, Branch Senior Scientist
Reregistration Branch 2
Health Effects Division [7509C]

TO: Thomas Harris, PM Team Reviewer
Insecticide/Rodenticide Branch
Registration Division [7505C]

HED has been asked to address DuPont's comments (letter of 5/17/99, Charles S. Baer, Ph.D. to Thomas Harris, EPA) to the celery field trial (MRID 44654301) review (DP Barcode D250016). Dupont states in part: ....in Table 2 of the study (pages 35-51), the column of data listed under the heading of "residues found oxime" represent all of the oxime and oxamyl residues converted to and reported as oxime. The column labeled "residues found oxamyl" is the residue level assuming all of the residues were present as oxamyl. The values found in the "residues found oxamyl" column is a calculated number generated by multiplying the "residues found oxime" number by a molecular weight conversion factor of 1.35. Use of either column of data yield a residue value that already represents the sum of oxime and oxamyl residue levels.

DuPont would also like HED to consider eliminating one field trial (site 8) from the study since the high residue levels could be due to the fact that at this site immature celery was harvested. DuPont states "We feel that this site should be disqualified since a grower would not harvest immature celery as it is unmarketable."

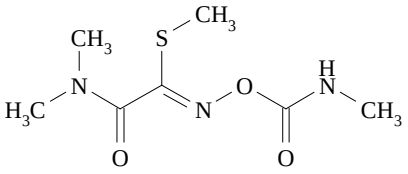
HED agrees that the celery field trial data were expressed as oxime, converted to oxamyl, and were inappropriately summed for inclusion in the review. Those results together with unusually

high residues on immature celery were then used as a basis for the recommendation of a 5 ppm tolerance and a 28 day post harvest interval (PHI).

HED agrees that immature celery would not normally be marketed and that high residues found on celery could be due to the harvesting of immature celery. Eliminating the residues found on the samples from this trial in consideration of a tolerance and PHI would suggest a 3 ppm tolerance and 14 day PHI is appropriate. However, in prior studies (MRID 43365402), DuPont has demonstrated oxamyl residues in/on celery, that were >3 ppm at 14 day PHI.

In light of the registrants comments, the available data were reexamined, deemed adequate, and may be used to reassess the established tolerance and determine an appropriate PHI. The combined residues of oxamyl and its oxime metabolite **do not exceed the established tolerance of 3 ppm in/on untrimmed celery harvested 21 days after last treatment**.

OXAMYL



PC Code 103801

BACKGROUND

Tolerances for residues of oxamyl in/on plant commodities are currently expressed in terms of the combined residues of oxamyl and its oxime metabolite, calculated as oxamyl equivalents [40 CFR § 180.303]. The Residue Chemistry Science Chapter for the Oxamyl Reregistration Standard Eligibility Decision (RED) Document (DP Barcode D244725, 4/22/98, J. Punzi) recommended that the established tolerance for the combined oxamyl residues of concern in/on celery be increased from 3 to 10 ppm based on the available celery field trial data reflecting the maximum registered use patterns and a PHI of 14 days.

Prior to the issuance of the Science Chapter, representatives from DuPont conferred with CBRS and SRRD on 11/21/94 and expressed the company's intention to conduct additional celery field trials for the purpose of maintaining the currently established 3 ppm tolerance level for celery. The studies were submitted in 1995 (MRID 43365402), reviewed, and found to support a 10 ppm tolerance and 14 day PHI (DP Barcode D209731, 10/25/95, D. Miller).

Subsequently, DuPont submitted a new celery field trial in 1998 (MRID 44654301) to support a 3 ppm tolerance and 21 day PHI. This study was reviewed by Dynamac Corporation, underwent a

secondary review in HED and showed that residues were less than 3 ppm at 28 days PHI. This decision was based on an incorrect accounting of the residues of oxamyl. Values for oxime and calculated values for oxamyl were inadvertently summed. The data summarized in Table 1 (below) should have been used to support the decision on tolerance and PHI (3 ppm tolerance and 21 day PHI).

Dupont has also noted that at one site in the 1998 trials immature celery was harvested (MRID 44654301, site 8) and that this site should be "disqualified" since a grower would not harvest immature celery as it is unmarketable. The original study makes a brief reference to this possibility as a footnote to Table 2 (p29) that high residue values were attributable to immature celery. In the discussion of the data in Dupont's 1998 submission (MRID 44654301) it was suggested that high residue values could have been the result of immature celery being harvested although no supporting data were provided. Table 2 (below) shows the range of oxamyl residues when the data for celery from trials at site 8 are excluded. The Agency agrees with the registrant that immature celery would not necessarily be harvested and could be eliminated from the field trials considered for the purpose of establishing a tolerance of 3 ppm and PHI of 14 days.

However HED also considered that the 1995 study demonstrated residues greater than or equal to 3 ppm at three of the test sites and for 9 of 42 samples tested at PHI of 14 days (Table 3). It therefore is reasonable to assume that residues incurred from the maximum labeled use rate of oxamyl could exceed 3 ppm at PHI of 14 days. Based on the two sets of field trial data the combined residues of oxamyl and its oxime metabolite are unlikely to exceed 3 ppm at 21 day PHI. Since the oxamyl label (Vydate L., EPA Reg. No. 352-372) has been modified (label accepted 5/6/99) to reflect a 21 day PHI, no additional celery field trial data are required.

Table 1. Oxamyl Residues for Treated Celery for Each Treatment at Each PHI

1998 trials (MRID 44654301), untrimmed celery, including 8 test sites (No. 1-8)

Treatment	PHI	Range of oxamyl residues found (ppm)
1[a]	14	<0.10-11.7*
	21	<0.10-1.92
	28	<0.10-1.35
2[b]	14	<0.10-13.5*
	21	<0.10-1.63
	28	<0.10-1.24
3[c]	14	<0.10-9.67*
	21	<0.10-2.12
	28	<0.10-2.50

* over tolerance

Table 2. Oxamyl Residues for Treated Celery for Each Treatment at Each PHI

1998 trials (MRID 44654301), untrimmed celery including 7 test sites (data from site no. 8 eliminated)

Treatment	PHI	Range of oxamyl residues found (ppm)
1[a]	14	<0.10-1.35
	21	<0.10-0.84
	28	<0.10-0.82
2[b]	14	<0.10-2.56
	21	<0.10-1.59
	28	<0.10-1.24
3[c]	14	<0.10-1.67
	21	<0.10-1.70
	28	<0.10-1.11

[a] Treatment 1 - Oxamyl was applied as a pretransplant banded soil incorporated treatment at 4.0 lb ai/A, followed by two foliar broadcast applications at 1.0 lb ai/A on an approximately 7-day schedule for a total of 6.0 lb ai/A (1x the maximum rate) using ground equipment.

[b] Treatment 2 - Oxamyl was applied as a banded application at 1.0 lb ai/A at transplanting followed by a second banded application at 1.0 lb ai/A three weeks later, and then followed by four foliar broadcast applications at 1.0 lb ai/A on an approximately 7-day schedule for a total of 6.0 lb ai/A (1x the maximum rate) using ground equipment.

[c] Treatment 3 - Oxamyl was applied as six foliar broadcast applications at 1.0 lb ai/A/application on an approximately 7-day schedule, resulting in a total application of 6.0 lb ai/A (1x the maximum rate) using ground equipment.

Table 3. Oxamyl Residues for Treated Celery for Each Treatment at 14 day PHI

1995 field trials (MRID 43365402)

Test Site No. and Location	Treatment 1 [a] Residues (ppm)	Treatment 2 [b] Residues (ppm)
1. Madera, CA	1.38, 1.46, 1.47	1.97, 2.30, 2.58
2. Donna, TX	0.67, 0.71, 0.72	0.76, 0.81, 1.46
3. Fallbrook, CA	1.86, 2.47, 2.51	2.93, 2.96, 4.63
4. Guadalupe, CA	3.51, 4.06, 8.03	1.17, 2.07, 2.19
5. Lake Jem, FL	0.70, 0.50, 1.16	1.10, 1.20, 1.55
6. Bradenton, FL	2.79, 3.00, 3.35	4.81, 5.54, 5.99
7. Allendale, MI	0.13, 0.16, 0.29	0.23, 0.41, 0.48

[a] Treatment 1 -Oxamyl was applied as a preplant banded application or shank injection application at 4 lb ai/A, followed by three foliar applications at 1 lb ai/A/application on an approximately 5-day schedule for a total of 7 lb ai/A (~1.2x the maximum rate) using ground equipment.

[b] Treatment 2 -Oxamyl was applied as six foliar broadcast applications at 1 lb ai/A/application (0.5 gal/A), resulting in a total application of 6 lb ai/A (~1x the maximum rate) using ground equipment.

CONCLUSIONS AND RECOMMENDATIONS

1. Celery samples from the submitted field trials were analyzed for residues of oxamyl **as** its oxime metabolite using a GC with flame photometric detection method (McKenzie Laboratories Method PRM-014) with reported limit of quantitation of 0.10 ppm for oxamyl. Based on concurrent method recovery data, Method PRM-014 is adequate for collection of residue data. Oxime data were converted to oxamyl equivalents by a molecular weight correction.

2. The stability of oxamyl residues in/on celery during frozen storage for up to 36 months has been demonstrated (CBRS No. 8843, DP Barcode D170851, 5/13/92, D. Miller). Storage stability of the oxime metabolite has also been demonstrated (CBRS No.15005, DP Barcode D210875, 4/11/95, D. Miller). HED concludes that the existing storage stability data support the celery field trials discussed in this report.

3. The celery field trial data are adequate and may be used to reassess the established tolerance and to determine an appropriate PHI. The combined residues of oxamyl and its oxime metabolite **did not exceed the established tolerance of 3 ppm in/on untrimmed celery harvested at 21 days following the last of multiple applications of a representative formulation at 1x the maximum registered seasonal rate**. Since the oxamyl label (Vydate L., EPA Reg. No. 352-372) has been modified (label accepted 5/6/99) to reflect a 21 day PHI, no additional celery field trial data are required.

cc: JSPunzi(RRB2),Oxamyl Reg. Std. File, SF, RF, LAN
RD/I: RRB2 ResChem Team 6/25/99
7509C:RRB2:John S. Punzi:CM2:Rm 712M':703-305-7727:6/25/99